MEETING THE LEGAL CONDITIONS FOR USER FEES IN FY 2013

PDUFA imposes three legal conditions that FDA must satisfy in order to collect and spend prescription drug user fees. A summary of how each of these legal conditions was satisfied in FY 2013 is shown below. Detailed explanations and calculations are described in Appendix A.

The first legal condition – FDA's overall Salaries and Expenses Appropriation (excluding user fees and rental payments to the General Services Administration (GSA)) must meet or exceed FDA's FY 1997 Salaries and Expenses Appropriation (excluding user fees and rental payments to GSA), multiplied by the adjustment factor. In FY 2013, FDA's appropriation for salaries and expenses was $2,347,014,000, excluding user fees and rent payments to GSA. FDA's FY 1997 Salaries and Expenses Appropriation excluding user fees and rent was $1,172,827,000 (rounded to the nearest thousand dollars), after applying the adjustment factor. Therefore, the first legal condition was satisfied.

The second legal condition – The amount of user fees collected for each fiscal year must be provided in that year's appropriation acts. The President signed the Consolidated and Further Continuing Appropriations Act, 2013 (Public Law 113-6) on March 26, 2013. It specified that $718,669,000 shall be derived from prescription drug user fees, and that prescription drug user fees collected in excess of this amount are also appropriated for FDA. Therefore, the second legal condition was satisfied.

The third legal condition – User fees may be collected and used only in years when FDA spends a specified minimum amount of appropriated funds (exclusive of user fees) for the review of human drug applications. This specified minimum is the amount FDA spent on the review of human drug applications from appropriations (exclusive of user fees) in FY 1997, multiplied by the adjustment factor. The specified minimum level for FY 2013 is $211,631,000 (rounded to the nearest thousand). In FY 2013, FDA obligated $299,267,407 from appropriations (exclusive of user fees) for the review of human drug applications. Because FDA spent more than the specified minimum amount in FY 2013, the third legal condition was satisfied.